Synergism in service and know-how

For more than 20 years, both companies have been working in the clinical development of gynaecological treatments successfully - dinox's specialist experience in gynaecological endocrinology is excellently complemented by SocraTec R&D's full-service CRO.

Whether in the development of contraceptives, hormone replacement therapy in postmenopausal women or medication for the treatment of infertility, endometriosis, premenstrual syndrome - we have the necessary knowledge and appropriate experience in all areas.

SocraTec R&D's CPU in Erfurt

- Perfectly equipped with 60 beds including intensive monitoring
- First-in-human studies
- Pharmacokinetic studies and bioavailability studies
- Drug-drug interaction and drug-food interaction studies

dinox's out-patient unit in Berlin

- Ideal setting with a well-trained team
- In-house gynaecologists
- Proof-of-concept and dose-finding phase II trials
- Specialized phase III studies

In Phase III, SocraTec R&D with its experienced project managers, monitors and international network of CROs can conduct multi-national, multi-centre studies - including the USA - always supported by the gynaecological expertise of dinox with their experience in countless international gynaecological registration projects.

The portfolio is completed by set-up of clinical development plans, consultancy in scientific advice procedures, modern data management and pharmacokinetics, modelling and biostatistics as well as professional medical writing.

dinox and SocraTec R&D together - your full-service partner for gynaecological development projects!

SocraTec R&D - a company profile

SocraTec R&D, a full-service clinical CRO, was founded in 1998. All key staff members of the company have far-reaching experience from many years in drug research and development. Our expertise covers a broad range from early phase clinical trials up to later stages of clinical development. From the beginning SocraTec R&D was active in the medical field of gynaecology. This expertise is extended by a strong network expanding over central and eastern Europe as well as the USA, and by the cooperation with dinox.

Our early phase Clinical Pharmacology Units

Our modern and functionally equipped main Clinical Pharmacology Unit with 54 beds is located in the centre of Erfurt, Germany

- Highly standardised conditions, ideal for PK, BE, DDI and FDI studies
- Technical equipment and expertise for early phase trials in gynaecology
- Excellently trained and qualified personnel with many years of experience in clinical trials and state of the art equipment and facilities

Our 6 beds intensive monitoring unit is located directly on the grounds of the full-service, maximum medical care hospital of Erfurt (former University Clinic)

- Ideal conditions for First-in-Human and First-in-Patient trials
- Direct cooperation with the Hospital for clinical infrastructure and (emergency) medical personnel with a state of the art intensive monitoring system

Late-phase experience for your development program

SocraTec R&D's experience in late-phase multi-national, multi-centre trials in gynaecological indications allows us to realise your complete development program. Our experienced monitoring team and our network of specialised CROs allow optimisation of country and site selection for high-quality studies with reliable recruitment rates Europe-wide as well as in the USA.

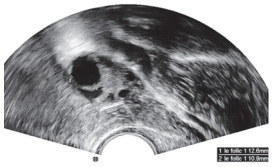
Full-service CRO

We offer the full service for your clinical development programme or act as a modular service provider, just as needed. This includes:

- Study planning with our clinical and statistical expert groups
- Clinical conduct of Phase I to IV clinical trials
- State-of-the-Art Project Management, Monitoring and Medical Writing
- Data Management, Pharmacokinetics and Biometrics fully compliant with with CFR 21 Part 11

dinox - a company profile

Founded in 1993, dinox is an internationally well-known key player in gynaecological drug development including - but not limited to - hormonal contraception, fertility treatment and endometriosis. Clinical activities are complemented by professional consultancy in gynaecological endocrinology focusing on clinical development programs, study design development, selection of pharmacodynamic assessments, and publication of study results. A huge number of scientific publications reflects the outstanding experience of dinox's gynaecological experts.



dinox operates its investigational site in Berlin (Germany) with easy access to a large population enabling fast recruitment, applying a large database of more than 4000 subjects and modern social-media based advertisement strategies. The site is equipped to deal with the logistic challenge of large numbers of subjects in complex phase II proof-of-concept and dose-finding studies. This allows efficient clinical performance even for high sample sizes in a mono-centric setting – a huge advantage for quality and standardisation.

Therefore, dinox is known for its outstanding data quality, a highly qualified and experienced team with dedicated in-house gynaecologists.

The gynaecological study methods include, amongst others:

- transvaginal ultrasonography (follicular growth, endometrial thickness, antral follicle count, ovulation scores, 3D ultrasonography, Doppler ultrasonography)
- endometrial biopsy
- cervical smear
- vaginal smear
- cervical mucus evaluation (Insler, WHO)
- IUD insertion/removal

Areas of research in gynaecology

Contraception

We are strong in Contraception! Phase I and PK studies in fertile and postmenopausal women are realised in Erfurt. Phase II proof-of concept, dose-finding and ovulation inhibition studies are conducted as single-centre study with up to 250 subjects in Berlin. Bleeding pattern, haemostasis and Pearl-Index studies are successfully run in multi-centre trials by an experienced team, where dinox participates as specialised site.

Investigation of the effects on lipids, carbohydrate metabolism (oral glucose tolerance testing) and haemostasis parameters requires high-quality blood sample collection and processing (i.e. according to the ECAT guidelines), a challenge our teams are well experienced in.

Fertility

The experts at dinox have been involved in the development of study designs that are tailor-made for each specific drug with its particular mechanism of action, such as GnRH antagonists, FSH and LH preparations, or progesterone for luteal phase support. With a clever study design, phase I, II, PK-PD and proof-of-concept studies can often efficiently be performed in healthy volunteers instead of patients seeking fertility treatment, as this allows for study conduct at a single site, with better standardisation of study procedures and short timelines. Our experts help you to optimise the development plan. Information gained from PK-PD data in healthy volunteers enables a valid prediction of the outcome of patient studies, leading to a significant cost and time reduction of the phase III program.

Endometriosis and fibroids

Several hormonal preparations for treatment of endometriosis or fibroids have been investigated in early phase with focus on dose finding and PK-PD studies in healthy volunteers, assessing treatment effects on endogenous hormone levels, ovarian activity and endometrial histology by biopsy. For smaller patient studies a multi-centre approach in Germany is possible, with extension to large size, multi-national phase III trials.

What we stand for

Our quality - your success

Reliability and Quality

In clinical research it's reliability and quality that counts and here we do not compromise - SocraTec R&D and dinox have a combined workforce of more than 150 skilled employees. Combined with our network of gynaecological sites, competence centres and referring gynaecologists, which provide reliable feasibility assessment, this is a unique setting ready for the conduct of complex clinical trials.

Our longstanding experience in all types of clinical trials allows a high level of scientific and medical expertise, excellent standardisation and active contribution of all employees to high-end study conduct. Further, our well-known quality level is reflected in the solid track record of our QA team in the management of audits and inspections. Both dinox and SocraTec R&D are successfully FDA inspected.

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